

REMARKS

Initially, the Examiner has objected to the specification and the claims due to certain typographical errors at page 8, line 19 and in claims 1 and 16. Applicant has amended the specification and claims as suggested by the Examiner. As such, withdrawal of the Examiner objections to the specification and the claims is respectfully requested.

The Examiner has also objected to claims 1-3, 5, 9-14, 18, 25 and 29-30 under 35 U.S.C. § 112, second paragraph. More specifically, the Examiner has indicated that claims 5, 9 and 18 are indefinite because they depend from cancelled claims. In addition, the Examiner believes that claims 1-3, 5, 9-14, 25 and 29-30 omit an essentially claim element. Applicant has corrected the dependencies of claims 5, 9 and 18. In addition, applicant has introduced the omitted step as suggested by the Examiner in claims 1-3, 5, 9-14, 25 and 29-30. In view of such amendments, applicant believes claims 1-3, 5, 9-14, 18, 25 and 29-30 are in proper form for allowance and withdrawal of the Examiner's rejections under 35 U.S.C. § 112, second paragraph, is earnestly solicited.

The Examiner has objected all of the claims predominately in view of newly discovered German Patent No. DE 19715421 to Eifler. More specifically, the Examiner has rejected claims 1 and 8-9 under 35 U.S.C. § 103(a) as being unpatentable over the Eifler '421 patent. Claims 1-2, 5, 8, 15, 18 and 20 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Cho, U.S. Patent No. 6,174,290 in view of the Eifler '421 patent. Claim 19 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over the Cho '290 patent as modified by the Eifler '421 patent and further in view of

Heilbrun et al., U.S. Patent No. 5,389,101. Claims 1, 8, 10-11, 25 and 27-30 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Lemmen, U.S. Patent No. 5,327,902 in view of the Eifler '421 patent and claim 13 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over the Lemmen '902 patent as modified by the Eifler '421 patent and further in view of the Heilbrun '101 patent. Claims 1-3, 8, 14-16 and 20-22 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Jackson et al., U.S. Patent No. 5,485,848 in view of Inukai et al., U.S. Patent No. 5,865,761 and the Eifler '421 patent. Finally, claims 1-2, 10, 12, 15 and 20 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Walters, U.S. Patent No. 3,067,749 in view of the Eifler '421 patent. Applicant has amended the pending claims to more particularly define the invention for which protection is sought. Reconsideration of the Examiner's rejections is respectfully requested.

Claim 1 defines an apparatus for sensing the amplitude of a signal traveling through a body. The apparatus includes an excitation device operatively engageable with the body. The excitation device generates the signal that travels along a nerve in the body. A sensing electrode is operatively engageable with the body under a pressure downstream of the excitation device for sensing the signal generated by the excitation device and traveling along the nerve in the body. The pressure mounting structure is operatively connected to the sensing electrode for controlling the pressure at which the sensing electrode engages the body. A pressure sensor is disposed adjacent the sensing electrode. The pressure sensor generates a pressure signal corresponding to pressure at which the sensing electrode engages the body. A controller is electrically connected to the pressure sensor for receiving the pressure signal and to the sensing electrode for receiving the signal sensed by the sensing electrode. The controller performs the steps of

determining a pressure normalization ratio in response to the pressure signal required from the pressure sensor. Thereafter, the pressure controller normalizes the required signals from the sensing electrode based on the pressure normalization ratio. As hereinafter described none of the cited references show or suggest an apparatus for sensing the amplitude of a signal traveling through the body that incorporates an excitation device that generates a signal that travels along a nerve in a body and a sensing electrode under a pressure that senses the signal that travels along the nerve. Further, as admitted by the Examiner, none of the cited references expressly teach the steps of determining the pressure normalization ratio and using it to normalize the acquired signal.

With respect to the Examiner rejection of claim 1 over the Eifler '421 patent, it is noted that the Eifler '421 patent is directed to an electric skin resistance measuring device that enables the measurement of the resistance of the human skin between a contact electrode and a measurement electrode. The pressure measurement device enables the measurement of the pressure applied through the measurement of the electrode on the human skin. A display device displays the measurement resistance and includes a data processing device that corrects the measurement resistance value in view of the measured pressure value.

Initially, it is noted that the measurement of skin resistance disclosed in the '421 patent and the apparatus of the present invention are directed to two distinct technologies. As is known, skin resistance is affected by the geometry of surface of the body where electrodes are placed. As such, pressure must be applied to the contacts in skin resistance measuring devices in order to insure the accuracy of the results. However, in the case of

nerve conduction studies, it has been found that pressure on the sensing electrode affects the amplitude of the sensed signal. Consequently, prior art devices intended to study nerve conduction have relied on the conduction velocity of a signal, and not amplitude of such signal. Nothing in the '421 patent contemplates the problems associated with apply pressure on the sensing electrodes during a nerve conduction study, much less suggesting a solution. Hence, applicant respectfully disagrees with the examiner's suggestion that the apparatus of claim 1 is obvious over the '421, since there is no suggestion of the problem to which applicant's claimed invention is directed and there is no teaching or suggestion in the '421 patent on how to solve such problem.

Further, unlike the structure disclosed in claim 1 of the present application, the electric skin resistance measuring disclosed in the '421 patent does not provide an excitation device that generates a signal that travels along a nerve in the body or a sensing electrode that senses the signal traveling along the nerve in the body. Further, since the skin resistance measurement device disclosed in the '421 patent merely calculates the skin resistance, there is no incentive or teaching in the '421 patent to determine a pressure normalization ratio and to use it to normalize the sensed signal as required by independent claim 1. Consequently, it is believed that independent claim 1 defines over the '421 patent.

Referring to the examiner's rejection of claim 1 over the Cho '290 patent in view of the Eifler '421 patent, it is noted that the Cho '290 patent discloses an ovulation period detecting apparatus for mammals. The apparatus includes a grip body incorporating a voltage generating means for applying voltage across a pair of electrodes; a sodium ion concentration detecting means incorporating an impedance detecting means for detecting

the impedance between the voltage applied electrodes; and an outputting means for indicating the condition of a vaginal mucus membrane on the basis of the detected impedance.

As noted with respect to the '421 patent, nothing in the '290 patent contemplates the problems associated with apply pressure on the sensing electrodes during a nerve conduction study, much less suggesting a solution. Further, unlike the apparatus of claim 1, the apparatus disclosed in the Cho '290 patent does not incorporate an excitation device that generates a signal that travels along a nerve in a body or a sensing electrode for sensing the signal traveling along the nerve. Further, since the ovulation period detecting apparatus merely detects the impedance on the vaginal mucus membrane, there is no suggestion or teaching to determine a pressure normalization ratio or to normalize a sensed signal based thereon. Consequently, applicant believes that the Examiner's rejection of claim 1 as being unpatentable over the Cho '290 patent in view of the Eifler '421 patent is improper.

With respect to the examiner's rejection of claim 1 over the Lemmen '902 patent in view of the Eifler '421 patent, it is noted that the Lemmen '902 patent discloses an apparatus for use in nerve conduction studies including a fixture for supporting a reference electrode, a recording of an electrode, a cathode and an anode, the distance between the cathode and the recording electrode being pre-selected and fixed. A controller causes an electrical pulse to be transmitted to the cathode. The distal latency and amplitude of the supramaximal stimulus response of the nerve being tested is determined and displayed.

The apparatus utilized in the '902 patent is intended to illuminate measurement errors consistent in the proper placement of electrode for nerve conduction studies. However, it is noted that nothing in the Lemmen '902 patent addresses the impact of pressure exerted on the sensing electrode on the signal amplitude during a nerve conduction study. This problem is not even contemplated in the '902 patent. Hence, there is no teaching or suggestion in the Lemmen '902 patent to provide a pressure sensor or a controller that determines a pressure normalization ratio and normalizes the signal received the sensing electrode based upon the pressure normalization ratio. Further, as noted above, given that the '421 patent merely measures the electrical resistance between two points of human skin, there is no incentive or teaching in the '421 patent to normalize the signal required from the sensing electrode based on a pressure normalization ratio. Hence, it is believed that claim 1 defines over the combination of the Lemmen '902 patent and the Eifler '421 patent cited by the Examiner.

Referring to the examiner's rejection of claim 1 over the Jackson et al., '848 patent in view of the Inukai et al., '761 patent and the Eifler '421 patent, it is noted that the Jackson et al. '848 patent discloses a portable blood pressure measuring device and a method of measuring blood pressure. The continuous blood pressure monitoring device includes a transistor mounted to detect arterial wall movement caused by blood flow through an artery of a user and the means for measuring the output signals of a transducer and actually converting the signal to systolic and diastolic blood pressure readings on a continuous basis. As noted by the Examiner, the Jackson et al., '848 patent does not teach or disclose the use of sensing electrode or a controller that determines a pressure normalization ratio and normalizes the signal from the electrode. Further, nothing in the

Jackson et al. '848 patent shows or suggests an excitation device that generates a signal that travels along a nerve in the body.

The Inukai et al. '761 patent discloses an apparatus that detects the blood pressure and electrocardiographic waveform of a living subject. However, similar to the '848 patent, nothing in the Inukai et al. '761 patent shows or suggests an apparatus for sensing an amplitude of a signal traveling through the body that incorporates an excitation device, that generates the signal that travels along a nerve in the body, or a sensing electrode for sensing the signal traveling along the nerve in the body. Such a structure is entirely absent from the Inukai et al. '761 patent. Further, as heretofore described, the '421 patent fails to teach or suggest an excitation device that generates the signal that travels along a nerve in the body, a sensing electrode that senses the signal traveling along the nerve in the body, or a controller that normalizes the acquired signal from the sensing electrode based on a pressure normalization ratio. Consequently, it is believed that claim 1 defines over the combination of the Jackson et al. '848 patent, the Inukai et al. '761 patent and the Eifler '421 patent.

Finally, the Examiner has rejected claim 1 as being unpatentable over the Walters '749 patent in view of the Eifler '421 patent. The Walters '749 patent discloses a clamping device by means of which electrodes may be fixed to the limbs of a patient during an examination performed with an electrocardiograph or phonocardiograph machine or during the performance of an electrocardiograph type examination wherein the electrode is used. It is noted that the Walters '749 patent does not disclose an excitation device that generates a signal that travels along a nerve in the body; a sensing electrode for sensing the signal traveling along the nerve; or the controller that

normalizes the acquired signal from the sensing electrode based on a pressure normalization ratio. These elements are entirely absent from the '749 patent. Further, as heretofore described, nothing in the '421 patent shows or suggests these limitations. Consequently, it is believed that claim 1 defines over the combination of the Walters '749 patent and the 'Eifler '421 patent.

In view of the foregoing, applicant believes that claim 1 defines over the cited references and is in proper form for allowance. Claims 2-3, 5, and 9-14 depend either directly or indirectly from independent claim 1 and further define an apparatus not shown or suggested in the art. It is believed that claims 2-3, 5 and 9-14 are allowable as depending from an allowable base claim and in view of the subject matter of each claim.

Referring to claim 15, an apparatus is defined for sensing a signal traveling through a body. The apparatus includes an excitation source operatively engageable with the body. The excitation source generates a signal that travels along a nerve in the body. The sensing electrode is operatively engageable with the body downstream of the excitation source for sensing the signal generated by the excitation source and traveling along the nerve in the body. A pressure source is configured to provide a pressure at which the sensing electrode engages the body. A pressure sensor is coupled between the pressure source and the sensing electrode. The pressure sensor generates a pressure signal representative of the pressure at which the sensing electrode engages the body. A controller is connected to the pressure sensor and to the sensing electrode. The controller acquires the pressure signal from the pressure sensor and the signal from the sensing electrode, determines the pressure normalization ratio in response to the pressure signal,

and normalizes the signal from the sensing electrode based on the pressure normalization ratio.

With respect to the Examiner's rejection of claim 15 based on the combination of the Cho '290 patent and Eifler '421 patent, it is noted that nothing in the 'Cho '290 patent shows or suggests an apparatus incorporating an excitation source that generates a signal that travels along the nerve in the body or a sensing electrode for sensing the signal traveling along the nerve in the body. Further, nothing in the Cho '290 patent shows or suggests normalizing a signal acquired from the sensing electrode based on the pressure normalization ratio. As noted above with respect to independent claim 1, the Eifler '421 patent cannot overcome the deficiencies of the Cho '290 patent. More specifically, the '421 patent does not disclose an excitation device that generates a signal that travels along a nerve in a body, a sensing electrode for sensing the signal traveling along the nerve in the body, or normalization of the signal acquired from the sensing electrode based on the pressure normalization ratio. Consequently, it is believed that claim 15 defines over the combination of the Cho '290 patent and the Eifler '421 patent.

Regarding the Examiner's rejection of claim 15 over the combination of the Jackson et al. '848 patent, the Inukai et al., '761 patent and the Eifler '421 patent, it is noted that none of the cited references show or suggest an apparatus incorporating an excitation source that generates a signal that travels along a nerve in a body, a sensing electrode that senses the signal traveling along the nerve, or the normalization of the signal acquired from the sensing electrode based on the pressure normalization ratio. Consequently, it is believed that claim 15 defines over the combination of the '848 patent, the '761 patent and the '421 patent.

With respect to the Examiner's rejection of claim 15 as being unpatentable over the Walters '749 patent in view of the Eifler '421 patent, it is noted that the combination of the Walters '749 patent and Eifler '421 does not show or suggest an excitation source that generates a signal that travels along a nerve in the body, a sensing electrode that senses a signal traveling along a nerve, or normalization of the signal acquired from the sensing electrode based on a pressure normalization ratio. As such, it is believed that claim 15 defines over the combination of the Walters '749 patent and the Eifler '421 patent.

In view of the foregoing, applicant believe that claims 15 is in proper form for allowance and such action is earnestly solicited. Claims 16 and 18-22 depend either directly or indirectly from independent claim 15 and further define an apparatus not shown or suggested in the art. It is believed that claims 16 and 18-22 are allowable as depending from an allowable base claim and in view of the subject matter of each claim.

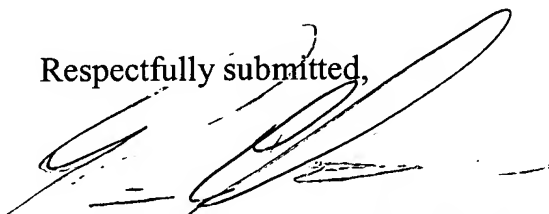
Referring to claim 25, a method is defined for sensing a signal traveling through the body. The method includes the steps of generating the signal with an excitation device such that signal travels along a nerve in the body. A sensing electrode is positioned on the body and a pressure is exerted on the sensing electrode against the body. The signal traveling along the nerve in the body is received with the sensing electrode and a pressure signal representative of the pressure with the sensing electrode engages the body is generated. A pressure normalization ratio is determined in response to the pressure signal and the signal received by the sensing electrode is normalized in response to the pressure normalization ratio.

As noted above, the Lemmen '902 patent does not contemplate the effects of pressure on a sensor measuring the amplitude of a signal traveling along a nerve in the body. The Eifler '421 patent merely discloses a device for the measurement of the electrical resistance between two points of the human skin. Hence, there is no teaching or incentive to combine the teachings of the Lemmen '902 patent and the Eifler '421 patent. Further, there is no suggestion or teaching in either of the cited references to normalize the signal received by the sensing electrode in response to a pressure normalization ratio. Hence, it is believed that independent claim 25 defines over the cited references and is in proper form for allowance. Claims 28-30 depend from claim 25 and further define a method not shown or suggested in the prior art. It is believed that claims 28-30 are allowable as depending from an allowable base claim and in view of the subject matter of each claim.

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Applicant believes that the present application with claims 1-3, 5, 9-16, 18-22, 25 and 28-30 is in proper form for allowance and such action is earnestly solicited. Applicant believes that no fees are due with submission. However, the Director is hereby authorized to charge payment of any additional fees associated with this or any other communication or credit any overpayment to Deposit Account No. 50-1170. A duplicate copy of this sheet is enclosed.

Respectfully submitted,



Peter C. Stomma, Reg. No. 36,020

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